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GLOBAL IP COUNSELORS, LLP 1233 20TH STREET, NW, SUITE 700 WASHINGTON, DC 20036-2680			EXAMINER KWAK, DEAN P	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,262	Applicant(s) HORIIE ET AL.	
	Examiner Dean Kwak	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/21/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (Claims 1-26) in the reply filed on 01/15/2009 is acknowledged.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **“extension line (Claims 7, 15, 20, 21, 24, 25)”**, **“a first point and a second point (Claim 18)”**, **“first stage measuring section (Claims 19 & 21)”**, **“first stage determining section (Claim 23 & 25)”** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: P59/L1-2, the reference numbers (i.e., 700, 705) should be corrected.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-18 & 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Brotherston et al. (US 6,399,361).

Regarding Claim 1, Brotherston et al. disclose a measuring chip (e.g., microsystem platform, Abstract), the measuring chip comprising:

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- a centrifugal separation tube (e.g., metering capillary, C37/L36 & Fig. 2 (202); Fig. 26 (902)) that centrifugally separates the target component from the sample by rotating the measuring chip around an axis of rotation;
- a first holding section (e.g., fluid chamber, C37/L48 & Fig. 2 (204)) provided in the bottom of the centrifugal separation tube; and
- a measuring section (e.g., read chamber, C11/L48 & Fig. 2 (210); also Fig. 26 (910)) connected to one end of the centrifugal separation tube.

Regarding Claim 1, Brotherston et al. meet all the structural limitations recited by the instant invention. Applicants' preamble recites "for separating and measuring a target component in a sample by rotation around each of a first axis and a second axis of rotation". A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It is noted that the device disclosed by Brotherston et al. is fully capable of meeting all the limitations of said claim.

Regarding limitations recited in Claim 1 which are directed to a manner of operating disclosed sample rack (e.g. "centrifugally separates the target component from the sample by rotating the measuring chip around the first axis of rotation", "non-target components in the sample are introduced into the first holding section by rotation around the first axis of rotation, and the first holding section holds the non-target components during rotation around the second

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axis of rotation”, “measuring the target component introduced from the centrifugal separation tube by means of rotation around the second axis of rotation”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding Claims 2-18, Brotherston et al. disclose all of the claim limitations as set forth above. In addition, Brotherston et al. disclose the measuring chip wherein:

- the centrifugal separation tube is U-shaped (see Fig. 2 (202) & Fig. 26 (902));
- an opening of the U-shaped centrifugal separation tube is 90 degrees or less (see Fig. 26 (902));
- the first holding section has a holding section main unit (Fig. 2 (204)), and a holding section connecting tube (e.g., capillary, C11/L34 & Fig. 2 (206)) that connects the holding section main unit and a centrifugal separation tube;
- the first holding section has a holding section main unit (Fig. 2 (204)), and a holding section connecting tube (e.g., capillary, C11/L34 & Fig. 2 (206)) that connects the holding section main unit and the centrifugal separation tube; and
 - the holding section connecting tube is formed in a tubular shape (e.g., capillary, C11/L34);

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- the first holding section has a holding section main unit (Fig. 2 (204)), and a holding section connecting tube (e.g., capillary, C11/L34 & Fig. 2 (206)) that connects the holding section main unit and the centrifugal separation tube;
- the chip further comprises a second holding section provided in the bottom of the centrifugal separation tube, the non-target components are introduced into the second holding section (e.g., waste reservoir, C30/L42 & Fig. 26 (915)) by rotation around the axis of rotation;
- the centrifugal separation tube has a first tube extending to the bottom of the centrifugal separation tube from a first end of the centrifugal separation tube connected to the measuring section, and a second tube extending from the bottom to a second end (see Fig. 26 (902));
 - a bypass tube (see one of metering capillaries in Fig. 2 (202); also Fig. 26 (903, 923, 909) acting as “bypass tube”) for connecting the first tube of the centrifugal separation tube to the second tube; and
 - a third holding section (e.g., overflow chamber, C30/L24 & Fig. 26 (905));
- the bypass tube and the connecting portion of the second tube form an angle of less than 90 degrees (see connection between Fig. 26 (909) & (902));
- the measuring section has a measuring section connection tube (e.g., capillary, C38/L12 & Fig. 2 (208)) that connects the centrifugal separation tube to the measuring section;
- the measuring section further comprises a measuring section main unit (Fig. 2 (210)); and a structure is formed in the measuring section main unit;

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- a regulation tube (e.g., valve, C11/L66 & Fig. 2 (213)) connected to the centrifugal separation tube and the measuring section, the regulation tube regulating the amount of sample centrifugally separated with the centrifugal separation tube; and
- the regulation tube has a first point and a second point in the interior thereof (see points above and below Fig. 2 (213)).

Regarding limitations recited in claims which are directed to a manner of operating disclosed sample rack (e.g. “distance to the second axis of rotation becomes smaller as the centrifugal separation tube extends from a first end of the centrifugal separation tube connected to the measuring section to the second end of the centrifugal separation tube (Claim 4)”, “distance between a first end of the centrifugal separation tube connected to the measuring section and the first axis of rotation is smaller than the distance between a second end of the centrifugal separation tube and the first axis of rotation (Claim 5)”, “extension line of the tube axis of the holding section connecting tube intersects with the first axis of rotation (Claim 7)”, “the distance between the holding section main unit and the first axis of rotation is larger than the distance between the holding section connecting tube and the first axis of rotation, and the distance between the holding section main unit and the second axis of rotation is larger than the distance between the holding section connecting tube and the second axis of rotation (Claim 8)”, “depth of the holding section main unit becomes deeper as the holding section main unit separates from the second axis of rotation (Claim 9)”, “area of a cross-section of the holding section main unit expands as the holding section main unit separates from the second axis of

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rotation (Claim 10)”, “the non-target components are held in the second holding section during rotation around the second axis of rotation (Claim 11)”, “the non-target components introduced into the third holding section by rotation around the first axis of rotation, and holding the non-target components during rotation around the second axis of rotation (Claim 12)”, “distance between a portion connecting the bypass tube to the first tube and the first axis of rotation is smaller than the distance between a portion connecting the bypass tube to the second tube and the first axis of rotation (Claim 13)”, “extension line of the measuring section connecting tube intersects the second axis of rotation (Claim 15)”, “that measures the target component introduced from the centrifugal separation tube by rotation around the second axis of rotation (Claim 16)”, “distance between the first point and the first axis of rotation is smaller than the distance between the second point and the first axis of rotation (Claim 18)”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding Claim 22, Brotherston et al. disclose a test chip (e.g., microsystem platform, Abstract) for determining a target component in a sample by rotation around a first axis and a second axis of rotation, comprising:

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- a centrifugal separation tube (e.g., metering capillary, C37/L36 & Fig. 2 (202); Fig. 26 (902));
- a first holding section (e.g., fluid chamber, C37/L48 & Fig. 2 (204)) provided in the bottom of the centrifugal separation tube;
- a measuring section (e.g., read chamber, C11/L48 & Fig. 2 (210); also Fig. 26 (910)) connected to one end of the centrifugal separation tube;
- at least one reagent reservoir (C29/L31 & Fig. 26 (917)) that stores a reagent therein;
- a mixing section (e.g., capillary junction, C29/L27 & Fig. 26 (907)) connected with the reagent reservoir and the measuring section;
- a photodetection path (C11/L50-65) connected to the mixing section, the photodetection path passing a mixed substance obtained by mixing the reagent and the target component; a light inlet connected with the photodetection path, the light inlet introducing light into the photodetection path; and a light outlet connected with the photodetection path, the light outlet removing light after passing through the interior of the photodetection path.

Regarding Claim 22, Brotherston et al. meet all the structural limitations recited by the instant invention. Applicants' preamble recites "for determining a target component in a sample by rotation around a first axis and a second axis of rotation". A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for

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completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It is noted that the device disclosed by Brotherston et al. is fully capable of meeting all limitations of said claim.

Regarding limitations recited in Claim 22 which are directed to a manner of operating disclosed sample rack (e.g. “centrifugally separates the target component from the sample by rotating the measuring chip around the first axis of rotation”, “non-target components in the sample are introduced in the first holding section by rotation around the first axis of rotation, and the first holding section holds the non-target components during rotation around the second axis of rotation”, “that measures the target components introduced from the centrifugal separation tube by rotation around the second axis of rotation”, “mixing section mixing the target component introduced from the measuring section by means of another rotation around the first axis of rotation, with the reagent introduced from the reagent reservoir by rotation around the first axis of rotation and/or the second axis of rotation”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brotherston et al. (US 6,399,361) in view of Hiroki et al. (JP 2004-109082; see English translation in IDS 04/21/06).

Regarding Claim 26, Brotherston et al. disclose all of the claim limitations as set forth above. However, Brotherston et al. fail to disclose a sampling needle to extract the sample.

Hiroki et al. disclose a microfluidic test chip (e.g., substrate, Fig. 1 (101)) as a blood analyzer, wherein the test chip further comprises a sampling needle (e.g., extraction means, Fig. 1 (103a)) connected with the centrifugal separation tube, the sampling needle serving to extract the sample (to conveniently draw sample, P4/[0006]).

Brotherston et al. and Hiroki et al. are analogous because these references are directed to use of microfluidic device to separate contents by adapting centrifugation (Abstracts).

It would have been obvious to use sampling needle to extract sample, as taught by Hiroki et al., to the test chip, as taught by Brotherston et al., to easily and conveniently draw sample from its location without having to use a transferring device.

Allowable Subject Matter

10. Claims 19-21 & 23-25 are allowed.

11. The following is an examiner's statement of reasons for allowance: The prior art of record fails to teach or suggest a plurality of measuring sections connected to the preceding measuring sections. Brotherston et al. disclose a plurality of measuring sections on a

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microsystem platform. However, Brotherston et al. fail to disclose a plurality of measuring sections that measure the component in stages of measurements.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Desmond et al. (PG Pub 2004/0018117) disclose a microfluidic device utilizing centrifugation to manipulate the fluid samples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dean Kwak whose telephone number is 571-270-7072. The examiner can normally be reached on M-TH, 5 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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27Feb09

/D. K./
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797